

IN THE SPECIFICATION:

Please amend the section title immediately preceding paragraph [0003] as follows:

BACKGROUND TO THE ~~OF THE~~ INVENTION

Please amend paragraph [0005] as follows:

[0005] In still other applications for ablative catheters, the catheter may need to be placed against a wall of a blood vessel or organ, for example, in heating ~~tumours~~ tumors for treatment of such ~~tumours~~ tumors. It is therefore desirable that a distal end of the catheter be substantially planar so that the distal end of the catheter assembly can be placed in contact with the wall of the vessel or organ.

Please amend paragraph [0006] as follows:

[0006] According to a first aspect of the invention, there is provided a catheter ~~assembly~~ assembly, which includes:

at least one introducer, the at least one introducer defining at least one passage;

an elongate tubular member slidably received within the at least one passage of the at least one introducer, the tubular member having a proximal end and a distal end and at least one lumen extending between the proximal end and the distal end; and

an elongate, shape-imparting element received in the at least one lumen of the tubular member, the shape-imparting element imparting a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer, a distal end of the shape-imparting element extending from the at least one lumen of the tubular member and being anchored proximally a distal end of the introducer.

Please amend paragraph [0013] as follows:

[0013] The shape-imparting element associated with the second tubular member, *i.e.* ~~i.e.~~, the second shape-imparting element, may extend beyond a distal end of the second tubular member. A distal end of the second shape-imparting element may be anchored distally with respect to the distal end of the second tubular ~~member~~ member, but proximally with respect to

the distal end of the first introducer. An anchor point of the first shape-imparting element may be in register with an anchor point of the second shape-imparting element. Both anchor points may be arranged on the first introducer.

Please amend paragraph [0015] as follows:

[0015] Each tubular member may be manufactured in accordance with the Applicant's manufacturing technique as disclosed ~~in its~~ in PCT Publication No. WO-02/32497-02/32497, entitled "An-electrical lead", Electrical Lead," the contents of which are incorporated herein by reference. The benefit of this manufacturing technique is that an unimpeded lumen is provided with conductors for the electrodes being at least partially embedded in a wall ~~of the~~ of a tubular member. Hence, a catheter assembly of small diametrical dimensions can be ~~formed~~ formed, thereby facilitating steering of the catheter assembly through the vascular system of a patient's body.

Please amend paragraph [0016] as follows:

[0016] Each shape-imparting element may be in the form of a shape memory alloy wire such as a Nitinol ~~wire~~ wire, which is in its superelastic state.

Please amend paragraph [0018] as follows:

[0018] According to a second aspect of the invention, there is provided a catheter ~~assembly~~ assembly, which includes:

at least one introducer, the at least one introducer defining a passage;

an elongate, tubular member slidably received within the passage of the at least one introducer, the tubular member having a proximal end and a distal end and a lumen extending between the proximal end and the distal end; and

an elongate, shape-imparting element received in the lumen of the tubular member, a distal end of the shape-imparting element extending beyond a distal end of the tubular member and being anchored proximally a distal end of the introducer, the arrangement being such that, when a distal portion of the tubular member is extended beyond the distal end of the introducer,

the shape-imparting element imparts, to the distal portion of the tubular member, a cranked arm portion extending transversely relative to a longitudinal axis of the introducer and a loop formation supported on the arm portion so that torsion imparted to a proximal end of the shape-imparting element causes rotation of the arm portion about the longitudinal axis of the introducer to effect adjustment of a diameter of the loop formation of the distal portion of the tubular member.

Please amend paragraph [0020] as follows:

[0020] Figure FIG. 1 shows a schematic, side view of a catheter assembly, in accordance with an embodiment of the invention;

Please amend paragraph [0021] as follows:

[0021] Figure FIG. 2 shows a schematic, end view of the catheter assembly; and

Please amend paragraph [0022] as follows:

[0022] Figure FIG. 3 shows a schematic, ~~three-dimensional~~ three-dimensional view of the catheter assembly.

Please amend paragraph [0024] as follows:

[0024] The catheter assembly 10 includes a first introducer in the form of a first sleeve 12 received within a passage 16 of a second introducer, also in the form of a second sleeve 14. The first sleeve 12 defines a passage 18.

Please amend paragraph [0025] as follows:

[0025] A first elongate tubular member 20 is slidably received within the passage 18 of the first sleeve 12. Similarly, a second tubular member 22 is slidably received within the passage 16 of the second sleeve 14. Each tubular member 20, 22 is manufactured in accordance with the Applicant's manufacturing ~~technique~~ technique, as disclosed in its in PCT publication number Publication No. WO 02/32497 entitled "An electrical lead"— Electrical Lead." As

indicated earlier in this specification, the contents of that earlier patent application are incorporated herein by reference.

Please amend paragraph [0026] as follows:

[0026] While not shown in the drawings, a plurality of electrodes are arranged at spaced intervals along the tubular members 20, 22. The electrodes on the tubular members 20 and 22 can be used for-sensing and/or ablation or-sensing, ablation and/or heating purposes.

Please amend paragraph [0027] as follows:

[0027] As illustrated, a distal portion 24 of the tubular member 20 is formed into a loop formation 26 when the tubular member 20 is extended from the first sleeve 12. Similarly, a distal portion 28 of the tubular member 22 is formed into a loop formation 30 when the tubular member 22 is extended from the second sleeve 14.

Please amend paragraph [0028] as follows:

[0028] As described in the Applicant's International Patent Publication No. WO-03/094764-03/094764, dated 9 May-2003-2003, and entitled "An ablation catheter", Ablation Catheter," the contents of which are also incorporated herein by reference, electrodes on the distal loop formation 26-can may, typically, be used for sensing of electrical activity in walls of a patient's vascular system with the proximal loop formation 30 being used for ablation purposes and being arranged, in use, at an ostium of the relevant pulmonary vein.

Please amend paragraph [0029] as follows:

[0029] However, there are applications where it is desired to place the distal loop formation 26 against a wall of a patient's organ, for example, for heat treating-tumours tumors. In that application, it is desirable that the distal loop formation 26 lies in a plane with no protuberances arranged distally of that plane. This is also advantageous when it is desired to steer the catheter assembly 10 through a patient's vascular system. It will be appreciated that any protuberances distally of the distal-end-end 40 of the first sleeve 12 could snag on a wall of the

patient's vein or artery as the catheter assembly 10 is being steered, resulting in difficulty in steering the catheter assembly 10, and possible damage to the patient's vascular system.

Please amend paragraph [0030] as follows:

[0030] To form the loop formations 26 and 30 in the tubular members 20 and 22, respectively, each tubular formation of the tubular members 20, 22 has an elongate shape-imparting element 32, 34 respectively, extending through the lumen of the tubular members 20, 22.

Please amend paragraph [0031] as follows:

[0031] Each shape-imparting element or wire 32, 34 is in the form of a length of shape memory alloy wire such as a Nitinol wire.

Please amend paragraph [0032] as follows:

[0032] The wire 32 protrudes beyond a distal end 36 of the tubular member 20. A distal end 38 of the wire 32 extends back-towards toward a proximal end of the catheter assembly 10 and is anchored on the first sleeve 12 proximally of a distal end 40 of the first sleeve 12.

Please amend paragraph [0033] as follows:

[0033] The wire 34 protrudes beyond a distal end 42 of the tubular member 22. A distal end 44 of the wire 34 is anchored to the first sleeve 12 approximately in register with the distal end 38 of the wire 32.

Please amend paragraph [0034] as follows:

[0034] With this arrangement, the loop formation 26 formed at the distal end of the catheter assembly 10 when the tubular member 20 is extended from the first sleeve 12 lies substantially in a plane extending transversely to a longitudinal axis of the catheter assembly 10.

Please amend paragraph [0035] as follows:

[0035] The wire 32 is pre-formed so that, when the tubular member 20 is extended beyond the distal end 40 of the first sleeve 12, the loop formation 26 is formed. The loop formation 26 is supported on a cranked arm portion 46. The cranked arm portion 46 ~~projects~~ projects from the distal end 40 of the tubular member 20 with an included angle 'A' (Figure FIG. 3) exceeding 90°. This facilitates the formation of a substantially planar loop formation 26. Similarly, when the tubular member 22 is extended from the second sleeve 14, the wire 34 imparts the loop formation 30 to the distal portion of the tubular member 22. Once again, the loop formation 30 is supported on a cranked arm portion 48. As is the case with the cranked arm portion 46 of the loop formation 26, the cranked arm portion 48 projects from the second sleeve 14 with an included angle 'B' (Figure FIG. 1) exceeding 90°. Once again, this facilitates the formation of a substantially planar loop formation 30.

Please amend paragraph [0037] as follows:

[0037] The portion of the wire 32 projecting beyond the distal end 36 of the tubular member 20 forms a bend 50 which is not covered by the tubular member 20. The bend 50 facilitates retraction of the tubular member 20 into the first sleeve 12 and the wire 32 lies substantially flush with an external surface of the first sleeve 12. Hence, a compact, small diameter arrangement is formed by the first sleeve 12 and its associated tubular member 20. Similarly, the wire 34 projecting beyond the distal end 42 of the tubular member 22 is cranked relative to the tubular member 22 to form a bend 52. Once again, this facilitates retraction of the tubular member 22 into the second sleeve 14 and facilitates the wire 34 lying flush against the outer surface of the tubular member 12. As with the case of the tubular member 20 and its first sleeve 12, a compact, smaller diameter arrangement of second sleeve 14 and tubular member 22 is provided.

Please amend paragraph [0038] as follows:

[0038] A proximal end of the wire 32 terminates in an actuating mechanism or actuator 54. Similarly, a proximal end of the wire 34 terminates in an actuating mechanism or actuator 56. The actuators 54, 56 are connected to a loop control mechanism (not shown) of a handle (also not shown) of the catheter assembly 10. For example, the loop control mechanism may be a thumb wheel for each wire 32 or it may be an electrically activated device.

Please amend paragraph [0039] as follows:

[0039] By means of the loop control mechanism, torsion is imparted to each of the wires 32, 34. When torsion is imparted to the wire 32, the cranked arm portion 46 of the tubular member 20 is caused to rotate about the longitudinal axis of the catheter assembly-10-as-10, as indicated schematically by arrows 58 in Figure FIG. 3 of the drawings. In so doing, the diameter of the loop formation 26 can be increased or decreased as desired. Similarly, by imparting torsion to the wire 34, the cranked arm portion 48 of the tubular member 22 is caused to rotate about the longitudinal axis of the catheter assembly-10-as-10, as indicated schematically by the by arrows 60. Once again, this facilitates increasing or decreasing the diameter of the loop formation-30-as-30, as desired.

Please amend paragraph [0040] as follows:

[0040] It is, accordingly, an advantage of the invention that a catheter assembly 10 with adjustable loop formations or loops 26, 30 is formed. The absence of any distal support members for supporting the loops 26, 30 or driving the loops 26, 30 torsionally results in a more compact, smaller diameter catheter assembly 10. This greatly facilitates steering of the catheter assembly 10 through-the a vascular system of a patient's body. In addition, the fact that no protuberances are required distally-of the distal of loop formation 26 of the catheter assembly 10 means that the loop formation 26 can be placed in contact with a wall of a patient's vessel or organ to facilitate heat treatment of that vessel or organ, for example, in the treating of tumours tumors. In addition, the absence of any protuberances distally of the distal end of the tubular

member 20 of the catheter assembly 10 facilitates steering of the catheter assembly 10 through the vascular system of a patient's body.